UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,134	09/14/2006	Irina Velikyan	PH0334	7198

36335 7590 09/21/2007

GE HEALTHCARE, INC.
IP DEPARTMENT
101 CARNEGIE CENTER
PRINCETON, NJ 08540-6231

EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
09/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,134	VELIKYAN ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-15 are pending in the application. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

Response to Arguments

1. Applicant's arguments filed 9/5/07 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griffiths et al. (WO03/059397) in view of the combined disclosures of Yngve (Int. Diss. Abs. **2001**, *62*) and Bottcher et al. (US 5,439,863) and in further view of Maier-Borst et al. (GB 2056471A) as stated in the office action mailed 5/11/07.

4. Applicant asserts that Griffiths et al. does not disclose the preparation of the agents via microwave acceleration.

5. The reference of Griffiths et al. was not used to teach of the preparation of the agents via microwave acceleration but to provide for the ^{68}Ga radiolabeled NOTA or DOTA and their use in PET. The ^{68}Ga- DOTA may be further linked to a peptide for targeting a specific cell, organ, tumor, etc. Griffiths et al. was also used to teach of the

purification of $^{68}Ge/^{68}Ga$ via in-house titanium dioxide generator which can be fitted with an anion-exchange membrane.

6. Applicant asserts that Griffiths et al. does not disclose the anion exchanger comprising quaternary amine functional groups, polystyrene-divinylbenzene and HCO_3^- as counterions.

7. The reference of Griffiths et al. teaches that the $^{68}Ge/^{68}Ga$ via in-house titanium dioxide generator can be fitted with an anion-exchange membrane. The counterion of the exchanger may be an appropriate buffer than is useful in the pH 2-6 range which includes a carbonate buffer which is well known in the art (p13, paragraph 1) and the Q5F cartridge is a quaternary ammonium cartridge. The reference of Maier-Borst et al. teaches of the purification of ^{68}Ga via an anion exchange column of quaternary ammonium groups incorporated into a matrix of styrene and divinylbenzene. In combination with the reference of Griffiths et al., it would be obvious to one skilled in the art that the quaternary ammonium anion exchanger of Griffiths et al. can be substituted for the anion exchanger of Maier-Borst et al. (quaternary ammonium groups incorporated into a matrix of styrene and divinylbenzene) as they are both drawn to the same utility of the separation/purification of ^{68}Ga.

8. Applicant asserts that Yngve did not use microwave heating to carry out the coordination chemistry (complexation of gallium by chelates).

9. The reference of Yngve was not used to teach of microwave heating to carry out the coordination chemistry (complexation of gallium by chelates) but to teach of the preparation of a phosphorothiolated ^{68}Ga-DOTA-oligonucleotide and a ^{68}Ga-DOTA-

octreotide for use in PET. In combination with Griffiths et al., it would be obvious to substitute the oligonucleotide of Yngve for the peptide of Griffiths et al.

10. Applicant asserts that Bottcher et al. concerns inorganic chemistry of salts and not coordination chemistry of the instant invention.

11. Bottcher et al. teaches of the production of neutral metal complex salts with ligands having different chemical structures coordinated/multitoothed chelating agents about the central metal atom in substantially quantitative yield and high purity via microwave (column 2, lines 30-33; column 3, lines 45 and 55-59) which is clearly coordination chemistry.

12. Applicant asserts that Maier-Borst et al. is drawn to the synthesis of an anion exchange resin for the separation of gallium-68 from germanium-68 avoiding the use of EDTA for elution as it was done before 1980s.

13. The reference of Maier-Borst et al. teaches of the purification of ^{68}Ga via an anion exchange column of quaternary ammonium groups incorporated into a matrix of styrene and divinylbenzene. In combination with the reference of Griffiths et al., it would be obvious to one skilled in the art that the quaternary ammonium anion exchanger of Griffiths et al. can be substituted for the anion exchanger of Maier-Borst et al. (quaternary ammonium groups incorporated into a matrix of styrene and divinylbenzene) as they are both drawn to the same utility of the separation/purification of ^{68}Ga.

Double Patenting

14. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

15. Claims 1,3-7 and 15 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 8-14 of copending Application No. 10/552,206 as stated in the office action mailed 5/11/07.

16. Claims 1,3-6 and 9-14 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-4,8-13 of copending Application No. 11/358,681 as stated in the office action mailed 5/11/07.

Applicant states that claims will be amended or canceled if the instant application is indicated to be allowable. Terminal disclaimers have not been filed and therefore the rejections are maintained.

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29

USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,2,8-15,18, and 19 of copending Application No.10/552,206 as stated in the office action mailed 5/11/07.

Claims 1-14 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims1-5 and 8-14 of copending Application No. 11/358,681 as stated in the office action mailed 5/11/07.

Applicant states that terminal disclaimers will be filed once the instant application is indicated to be allowable. Terminal disclaimers have not been filed and therefore the rejections are maintained.

Conclusion

No claims are allowed at this time.

18. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
September 18, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER